REMARKS

Prior to this Amendment, claims 63-85 were pending in this application. Herewith, Applicant has amended claims 63, 69-72, 83 and 84 and canceled claim 68. New claims 86-93 have been added. Support for the newly added claims can be found in the specification, for example, on pages 18-20 of the specification and in the claims as originally filed. Therefore, claims 63-67 and 69-93 are pending with claims 63, 80-83 and 93 being independent claims. No new matter has been added.

Allowable Subject Matter

Applicant thanks the Examiner for indicating that claims 80-82 are allowed and that claims 69-71 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Interview with Examiner VanderVegt

Applicant respectfully thanks Examiner VanderVegt for conducting an interview with Applicant's representative. During the interview, the outstanding rejections as well as possible claim amendments were discussed. Although no final agreement was reached, Applicant thanks the Examiner for indicating that claims to antibodies or antigen-binding fragments thereof that contain all of the CDRs of any one of the deposited antibodies would be found allowable. Applicant further thanks the Examiner for indicating that compositions comprising the deposited antibodies or antigen-binding fragments thereof would also be found allowable.

Rejections under 35 U.S.C. §112

The Examiner has rejected claims 63-68, 72-79 and 83-85 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner has argued that the specification does not disclose the amino acid sequence of any of the monoclonal antibodies or of any portion thereof. The Examiner has also argued that the specification does not disclose that any of the six CDR regions from any of the three deposited antibodies is capable of binding

human mannose-binding lectin (MBL) on its own. Therefore, the Examiner concludes that possession is not demonstrated due to the lack of a description of the actual structure of the individual CDRs and a lack of a description of the actual binding properties of the individual regions.

Applicant respectfully disagrees. First, Applicant notes that the Examiner has admitted that the deposit of the antibodies demonstrates possession of the deposited antibodies and antigen-binding fragments thereof (page 4, lines 2-3, of the present Office Action). Antigen-binding fragments include the CDRs of the antibodies and are discussed further below. It follows, therefore, that the currently pending claims satisfy the written description requirement, as the claims relate to these same deposited antibodies and antigen-binding fragments. Instead, however, the Examiner argues that this is not the case seemingly because of the supposed lack of sequence information of the CDRs. While the sequence information is not required to satisfy the written description requirement of the present claims, which do not recite specific sequences, Applicant maintains that the deposit of the antibodies necessarily provides the sequences for the deposited antibodies and fragments. The Examiner has ignored the conclusion of the Federal Circuit, which found that the deposit of cell lines was sufficient to not only satisfy the written description requirement but also was sufficient to adequately support claims to the sequences expressed by the deposited cell lines. Enzo Biochem v. Gen-Probe, 323 F.3d 956, 964 (Fed. Cir. 2002). Similarly to Enzo Biochem v. Gen-Probe, the deposit of the hybridomas by Applicant provides sufficient written description of not only the antibodies produced by the deposited antibodies and fragments of the antibodies but also the sequences of these antibodies and fragments.

Secondly, the specification indeed provides the description of the binding properties of the individual CDRs of the claims. The specification describes, for example, on page 18 that these CDRs bind MBL. Nothing further is required of Applicant, as this is indeed conveyed with reasonable clarity. One of ordinary skill in the art would clearly recognize that the Applicant has invented what is claimed. This is in conformity with Vas-Cath Inc. v. Mahurkar, which was cited by the Examiner. The Examiner has failed to establish that this does not satisfy the written description requirement, namely that Applicant's assertions are not reasonably clear and would not be recognized by one of ordinary skill in the art. Instead it seems that the Examiner bases

this part of the rejection on his own opinion and doubt that the CDRs of the antibodies are capable of binding MBL. However, this is not the correct standard. In order for this rejection to be applicable to the current claims, it must be shown that one of ordinary skill in the art would not recognize in the application a description of what is claimed, and this has not been demonstrated.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 63-68, 72-79 and 83-85 under 35 U.S.C. §112, first paragraph, as the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The Examiner argues that the CDR3 regions of the deposited antibodies have not been sequenced and the ability of any of the CDR regions to bind MBL on its own has not been shown.

Applicant respectfully disagrees. First, again contrary to the Examiner's assertion that the sequences are not provided by Applicant's disclosure, Applicant maintains that this is not the case. The sequence information is inherently provided by the deposit of the antibodies, as explained above. In addition, it would be certainly routine for one of ordinary skill in the art to obtain the sequence information from the deposited antibodies. Therefore, even if *arguendo* the sequence information was not provided through the deposit of Applicant's antibodies, the Examiner can hardly maintain that it would require undue experimentation for one of ordinary skill in the art to obtain such information. Therefore, one of ordinary skill in the art would be able to obtain the necessary sequence information to engineer the antibodies of the claims. Outside of the supposed lack of sequence information, the Examiner has not indicated that one of ordinary skill in the art would face any further experimental difficulties in making the antibodies or fragments thereof of Applicant's claims.

Second, the Examiner argues that the ability of any of the CDRs to bind MBL has allegedly not been shown. Applicant reminds the Examiner that working examples are not required. In addition, the only justification provided for doubting Applicant's assertions is the teachings of Janeway et al. Applicant maintains that this has been sufficiently rebutted. As argued previously, Janeway et al. teach that all CDRs are involved in binding of whole

antibodies to antigen; however, Janeway et al. in no way demonstrate that one of ordinary skill in the art would not be able to make other MBL binding antibodies or fragments that contain a CDR3 region as provided by Applicant based on the guidance provided by Applicant's specification and the high level of skill in the art. The teaching that other CDRs are involved in antigen binding is not a teaching that fragments of the antibody as short as a single CDR would fail to bind its specific antigen, nor is it a teaching that antibodies cannot be engineered with one or a set of CDRs.

In addition, to these arguments, Applicant has submitted to the Examiner references that show that CDR3 containing peptides can be made and can bind antigen consistent with Applicant's assertions. This evidence is sufficient to rebut the Examiner's arguments in regard to Janeway et al. In the face of Applicant's arguments, the Examiner must establish a reasonable basis to continue to doubt that CDR3 containing antibodies or fragments thereof that, in some embodiments, do not contain any or all of the other CDRs of the deposited antibodies, would be expected to bind MBL. It is not sufficient for the Examiner to merely point out that the references Applicant has submitted are in regard to other antigens and other antibodies. The references directly counter the Examiner's assertions in regard to Janeway et al. Therefore, the Examiner must demonstrate more to be able to maintain this rejection.

As argued previously, the level of skill in the relevant art of biological sciences and antibody production is very high, and the highly skilled artisan is reasonably able to produce the antibodies or antibody fragments of the rejected claims based on the guidance provided in Applicant's specification, including the deposited antibodies, and the knowledge of those in the art. Such a reasonable expectation is sufficient to satisfy the enablement requirement. Applicant maintains that one of ordinary skill in the art would be able to make an antibody or fragment thereof that contains a CDR3 region of the deposited antibodies and determine the ability of the antibody or fragment thereof to bind human MBL using only routine methods known in the art and the teachings of the specification.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 63-68, 72-79 and 83-85 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner has argued that claim 63 is ambiguous and unclear in the recitation of "comprising: a CDR3 of a monoclonal antibody" in light of dependent claim 68, which provides the further limitation that the antibody or fragment thereof of claim 63 is a monoclonal antibody. Without conceding the correctness of the Examiner's rejection, Applicant has canceled claim 68 and amended claim 63 to be drawn to a monoclonal antibody.

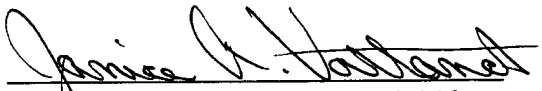
Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the application in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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